Comparison of Radical Prostatectomy Techniques: Open, Laparoscopic and Robotic Assisted

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ABSTRACT

Introduction: To review the current status of laparoscopic radical prostatectomy (LRP) and robotic assisted radical prostatectomy (RALP) in relation to radical retropubic prostatectomy (RRP) in the management of localized prostate cancer.

Materials and Methods: Between 1982 and 2007 published literature was reviewed using the National Library of Medicine database and the following key words: retropubic, laparoscopic, robotic, robot-assisted, and radical prostatectomy. Special emphasis was given to the technical and cost considerations as well as operative, functional and oncologic outcomes. In particular, reports with pioneering work that have contributed to the evolution of the technique, presenting comparative outcomes and with large series encompassing intermediate/long term follow-up, were taken into account.

Results: After intermediate term follow-up, LRP and RALP achieved similar oncologic and functional results compared to RRP. However, LRP and RALP were associated with decreased blood loss, faster convalescence and better cosmetics when compared to RRP. The RALP technique is undoubtedly more expensive.

Conclusions: The oncologic and functional outcomes for LRP and RALP are similar to RRP after intermediate term follow-up. Long term follow-up and adequately designed studies will determine the inherent advantages and disadvantages of the individual techniques in the management of localized prostate cancer.

Key words: prostate cancer; prostatectomy; laparoscopy; robotics

INTRODUCTION

Prostate cancer accounts for approximately one third of cancer in men in the United States. Eighty-six percent of prostate cancer diagnosed in 2004 was localized with 5-year survival rates approaching 100% (1). Based on excellent survival rates, radical prostatectomy is considered the standard treatment for the management of localized prostate cancer (2).

Retropubic Radical Prostatectomy (RRP) was first reported by Millin in 1947 (3). However, the procedure was associated with significant blood loss, incontinence, impotence and prolonged convalescence. In the early 1980s, Walsh laid the foundations of anatomic RRP with better understanding of the prostate anatomy, specifically the dorsal vein complex and neurovascular bundle (NVB) (4). These results were associated with better functional outcomes without compromising oncologic principles.

The variability of RRP outcomes, introduction of laparoscopy in the urological armamentarium and the success of less invasive treatment alternatives (i.e. brachytherapy) in prostate cancer, have acceler-
ated the development of laparoscopic pelvic surgery (5). Schuessler et al. performed the first laparoscopic radical prostatectomy (LRP) in 1991 (6). Of note, the LRP technique has been refined and standardized by Guillonneau and Vallancien in the late 1990s and the procedure has gained popularity since then (7). In addition to the conventional advantages of minimal invasive surgery and reduced blood loss, the LRP technique, in expert hands, is safe and effective, and provides oncologic outcomes comparable to that of open RRP (7,8). However, LRP is a complex procedure associated with a steep learning curve and limited ergonomics.

Robotic assisted laparoscopic prostatectomy (RALP) was first reported by Abbou et al. in 2000 (9). RALP has been popularized by Menon et al. with an intention to decrease the steep learning curve of LRP while accomplishing the advantage of a minimally invasive technique (10). Advantages of the RALP technique include the 3-dimensional stereoscopic visualization, intuitive finger-controlled movements and the Endowrist technology (Intuitive Surgical, Sunnyvale, CA, USA) (11). Furthermore, improved ergonomic surgery can be achieved by a comfortably seated surgeon.

The RRP is the reference standard for the surgical management of localized prostate cancer. With wider availability of the minimally invasive radical prostatectomy techniques, there is a debate regarding what the standard treatment will be for the management of localized prostate cancer in the near future. It is also open to discussion as to whether experienced open surgeons should learn minimally invasive techniques. There are no prospective randomized studies, to our knowledge, comparing the three techniques (RRP vs. LRP vs. RALP) to date. In comparing the three techniques, several issues such as perioperative, functional and oncologic outcomes need to be addressed. Unquestionably, achieving optimum cancer control is the most important determinant followed by favorable functional outcomes. Another factor that influences treatment acceptance is the cost.

It is clearly important to address these issues in the urological literature. Therefore, in this review, we present the evolution and the recent data on the outcomes of RRP, LRP and RALP in the contemporary urological literature with a special emphasis on the technique, cost, operative, functional and oncologic outcomes.

**SURGICAL TECHNIQUE**

The standard surgical technique for RRP was described by Walsh (4). Other urologists have used additional anatomic and technologic advances to minimize morbidity associated with the procedure. Slabaugh and Marshall reported modified incisional techniques and noted that the mini-laparotomy RRP technique was associated with less operating room (OR) time and reduced cost compared to LRP (12). Mini-laparotomy was performed using an 8 cm low midline incision, wherein a laparoscopic camera lens was used for visualization. Sved et al. reported a RRP technique with a modified Pfannenstiel incision associated with better cosmetic results, less postoperative pain and lower analgesic requirement (13).

Four different LRP techniques including the transperitoneal antegrade technique, transperitoneal retrograde technique, extraperitoneal antegrade technique and extraperitoneal retrograde technique have been described (14). The antegrade transperitoneal approach is preferred at the Cleveland Clinic. Using the transperitoneal or the extraperitoneal approach, the senior author has performed more than 750 LRPs at our institution since 1999.

Our transperitoneal LRP technique has been previously reported (15). Briefly, the patient is placed in a modified lithotomy position with the arms adducted by the patient’s side. The table is set in a 15-30 degree Trendelenburg position. Initially, five ports are placed in a fan-array (Figure-1). Bowel loops are gently retracted out of the pelvic cavity. An inverted U-shaped peritoneotomy incision along the undersurface of the anterior abdominal wall is made. Subsequently, the endopelvic fascia is freed from the fatty tissue bilaterally and incised using a J-hook electrocautery or cold endoshears. The Foley catheter is replaced by a metallic urethral dilator to enhance needle orientation during dorsal vein ligation. The dorsal vein complex ligature is created with a 2-0 Vicryl (CT-1 needle) stitch. The posterior bladder neck is deeply scored with a J-hook electrocautery at the proposed line of transection at a safe distance.
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IURPWKHXUHWHULFRUL¿FHV7KHYDVGHIHUHQVLVFOLSSHG with a Hem-o-lock clip and divided. The NVB is released in an antegrade manner along the convexity of the prostate, using a combination of sharp scissor cuts and gentle blunt teasing with a soft laparoscopic Kittner. The dorsal vein complex is divided, followed by apical dissection and urethral transection. Urethrovesical anastomosis is accomplished with a water-tight double-needle running suture technique using 2-0 Monocryl in two different colors. A 20 Fr Foley catheter is inserted into the bladder. A Jackson-Pratt drain is placed in the pelvis, the specimen is removed by extending the umbilical port site incision and port sites are closed.

The extraperitoneal approach provides a rapid access to the space of Retzius, minimizes bowel complications and intra-abdominal organ damage. However, recent studies comparing transperitoneal versus extraperitoneal approaches have not found any significant differences (16,17). The extraperitoneal approach may be preferable in obese patients as it may shorten the distance between the trocar insertion site and operative field, and in patients with previous abdominal surgery where time-consuming adhesiolysis is avoided and the risk of bowel injury is minimized (14).

LRP renewed interest in the periprostatic neuroanatomy because of the superior image quality and enhanced magnification. Technical modifications during LRP have mainly focused on the nerve sparing procedure. Gill et al. have reported the use of intraoperative transrectal ultrasound monitoring to identify the course of the NVBs (18). With this technique, it was possible to substantially reduce the positive surgical margin rate (19).

Similar to the LRP technique, the RALP technique has also been described using the intraperitoneal or extraperitoneal approaches, but most surgeons prefer the transperitoneal approach because of larger working space and the potential for tension free urethrovесical anastomosis. The Da Vinci robotic system (Intuitive Surgical, Inc., Sunnyvale, CA) is the only robotic platform available providing superior illumination of the surgical field. We have performed more than 250 RALPs at the Cleveland Clinic using either the transperitoneal or the extraperitoneal approach. The basic surgical principles do not differ from the LRP technique. Briefly, a 6-port strategy is used with an initially placed 12 mm port at the left superior margin of the umbilicus. Port positioning is similar for both the transperitoneal and extraperitoneal approaches (Figure-2). For the transperitoneal approach, access is achieved using the Veres needle, while extraperitoneal approach involves cut-down and dilation of the extraperitoneal space with 10 mm PDB™ System Balloon (Tyco Healthcare, Mansfield, MA, USA) which is advanced in the midline between the rectus muscle and into the retropubic space prior to inflation. The prostate is exposed, the endopelvic fascia incised bilaterally and the dorsal venous complex is oversewn with Nº.1 Vicryl suture. The bladder neck is incised and the seminal vesicles and vasa are dissected out. These are divided along with the prostatic pedicles using a harmonic dissecting scalpel. The endopelvic fascia is then reflected off the prostate preserving the NVBs. The urethra is divided and the prostate reflected cephalad. Remaining prostate-rectal fibers are divided and the prostate specimen placed in an Endocatch bag. Urethrovesical anastomosis is performed with 2/0 Monocryl and 2/0 Caprosyn sutures in a continuous running fashion.

![Figure 1 – Port placement during laparoscopic radical prostatectomy.](image-url)
OPERATIVE OUTCOMES

Regardless of the approach used, mortality associated with radical prostatectomy is low. The recently published reports comparing the different techniques have mainly focused on the perioperative outcomes such as OR time, estimated blood loss, analgesic requirement, length of hospitalization, duration of catheterization, and postoperative complications. Table-1 summarizes the perioperative outcomes of RRP, LRP and RALP from select large series in the published literature from pioneering centers of excellence.

In all approaches, small abdominal incision translates into low pain scores. Earlier reports suggested reduced analgesic requirements with LRP compared to RRP (8), though others reported comparable rates (20). The potential for blood loss is consistently reduced in the LRP and RALP series and is a result of the pneumoperitoneum pressure and excellent visualization. Likewise, overall complications appear to be marginally lower after LRP and RALP.

Traditionally, the duration of catheterization for RRP ranged between 2 to 3 weeks, but recent studies report shorter catheterization periods (7 to 10 days). For the laparoscopic and robotic techniques, the duration of catheterization is usually in the range of 5 to 7 days. OR time appears to be shorter for RRP compared to RALP and LRP, but increasing experience with minimally invasive approaches, OR times will probably decrease.

ONCOLOGIC OUTCOMES

The primary goal of prostate cancer surgery is to provide satisfactory oncologic outcomes. Although, overall and cause-specific survival rates provide the ideal measures in determining long-term oncologic control, biochemical progression and margin positivity are the two commonly used indices to assess oncologic outcomes following RRP, LRP and/or RALP. While RRP provides long-term oncologic control for up to 15 years, limited follow-up is available for the minimally invasive approaches. In patients who underwent RRP between 1998 and 2003 at the Mayo Clinic, the 3-year and 5-year PSA progression-free survival estimate rates were 99% and 98%, respectively (21). Guillonneau et al. evaluated their results in 1000 patients after LRP and reported an overall biochemical progression-free survival rate of 90.5% at 3 years (22). According to the pathologic stage, the biochemical progression-free survival rates were 92% for pT2a, 88% for pT2b, 77% for pT3a, and 44% for pT3b at a mean follow-up of 12 months. Rozet et al. reported 95% PSA progression-free survival rate at a mean follow-up of 12-months in a series of 600 patients who underwent extraperitoneal LRP (23). Rassweiler et al. reported PSA progression-free survival rates of 83% at 3 years and 73% at 5 years in 500 patients who underwent retrograde LRP (24). Patel et al. reported a PSA progression-free survival rate of 95% in 200 patients who underwent RALP with a mean follow-up of 9.7 months (25).
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Positive margin rate is another method of assessment of oncologic outcomes that is readily available giving a prediction for long-term oncologic outcome. Studies from large series demonstrated an overall positive surgical margin rate of 21-28% for RALP (Table-2).

The number of comparative studies (RRP vs. LRP vs. RALP) is limited in the literature. The true advantages and disadvantages of each technique will appear only after objective comparisons in prospective studies with long-term follow-up. DiMarco et al. noted no significant differences in positive margin rates between RRP (18.6%) and RALP (16.5%) (26). Similarly, there were no significant differences regarding the positive margin rate between RRP (19%) and LRP (22%) (27). In another study by Ahlerring et al., the positive surgical margin rate was 20% for RRP vs. 16.7% for RALP (28). None of these comparative studies showed any disadvantage in terms of oncologic outcomes for the minimally invasive approaches. Furthermore, there has been no report on port site recurrence following LRP or RALP.

FUNCTIONAL OUTCOMES

Continence

Many differences exist between definitions of continence and the way that the information is obtained. The best way to analyze this outcome is undoubtedly the use of validated questionnaires. Continence rate, basically defined as requiring one or no pad per day, is reported to be between 90-92% for RRP, 82-96% for LRP and 95-96% for RALP (Table-2).

In the Prostate Cancer Outcomes Study, Penson et al. reported continence rates of 90% at 24-month follow-up and 86% at 60-month follow-up in 1288 men who underwent RRP (29). Stolzenburg et al. reported a continence rate of 84% at 6-month follow-up and a 92% continence rate at 1-year fol
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low-up in 700 extraperitoneal LRPs (30). Regarding RALP, Ahlering et al. reported a 98% continence rate at 12-month follow-up in their initial series of 200 patients (28). Moreover, Menon et al. reported a continence rate of 96% in a series of more than 1100 RALP procedures (10).

It should be noted that patient selection, tumor characteristics, and surgeon experience may interfere with the outcomes in retrospective studies. Ongoing evaluation of continence with validated questionnaires is required to compare various techniques of radical prostatectomy. Data currently available suggests that similar rates for return to continence may be achieved for the three different techniques (Table-2).

**Potency**

Erectile function outcomes after radical prostatectomy depend on the urologist’s subjective impression, patient’s self statement, use of validated questionnaires and various types of definitions for potency. Unquestionably, the performance of a nerve sparing procedure is of critical importance as well as the postoperative use of topical or oral medications.

Su et al. reported 76% of intercourse rate at 1-year follow-up after bilateral nerve-sparing LRP (31). Menon et al., in a study of more than 1100 patients, reported an intercourse rate of 64% for men younger than 60 years and 38% for men older than 60 years at 6-month follow-up (10). Table-2 outlines the potency rates for RRP, LRP and RALP from select large series in the literature. The potency rates for RRP range from 46% to 67%, 66% following LRP, and 38% to 64% after RALP from select large series in the published literature.

When the ability to perform sexual intercourse after a nerve sparing procedure was compared between the RRP and LRP, similar results, overall, were found (14). After stratifying these patients according to age and unilateral or bilateral nerve-sparing procedure.

**Table 2 – Oncologic and functional outcomes of RRP, LRP and RALP from select series.**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Technique</th>
<th>N of Patients</th>
<th>Positive Margin Rate (%)</th>
<th>Continence Rate (%)</th>
<th>Potency Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York University (Hsu EL et al.) (35)</td>
<td>RRP</td>
<td>1024</td>
<td>21</td>
<td>91</td>
<td>46</td>
</tr>
<tr>
<td>Washington University (Catalona et al.) (36)</td>
<td>RRP</td>
<td>1870</td>
<td>21</td>
<td>92</td>
<td>67</td>
</tr>
<tr>
<td>Heilbronn (Rassweiler et al.) (8)</td>
<td>RRP</td>
<td>219</td>
<td>28.7</td>
<td>90</td>
<td>N/A</td>
</tr>
<tr>
<td>Heilbronn (Rassweiler et al.) (8)</td>
<td>LRP</td>
<td>438</td>
<td>23.7</td>
<td>95.8</td>
<td>N/A</td>
</tr>
<tr>
<td>Montsouris (Guillonneau et al.) (37)</td>
<td>LRP</td>
<td>550</td>
<td>16.7</td>
<td>82.3</td>
<td>66</td>
</tr>
<tr>
<td>Cleveland Clinic (4/1999-10/2006)</td>
<td>LRP</td>
<td>759</td>
<td>20</td>
<td>96</td>
<td>N/A</td>
</tr>
<tr>
<td>Vattikuti (Menon et al.) (38)</td>
<td>RALP</td>
<td>200</td>
<td>6</td>
<td>96</td>
<td>38-64</td>
</tr>
<tr>
<td>Cleveland Clinic (8/2001-10/2006)</td>
<td>RALP</td>
<td>216</td>
<td>6.4</td>
<td>95</td>
<td>N/A</td>
</tr>
</tbody>
</table>
procedure, the rate of potency in patients younger than 55 years old undergoing LRP with unilateral nerve-sparing procedure was 36.4% vs. 36.7% for RRP. For the same group, but with bilateral nerve-sparing procedures, the potency rate for LRP was 77.8% vs. 69% for RRP. In patients between 55 to 65 years old with unilateral nerve-sparing procedures, the potency rate was 31% for LRP and 20.7% for RRP. In this group, but with bilateral nerve-sparing procedure, the potency rate for LRP was 60% vs. 52% for RRP. In patients older than 65 years old, the potency rates were lower, but comparable results were found for the two groups.

In a single institutional study, Abbou et al. reported similar potency rates at 3, 6, 12 months for patients undergoing RRP and LRP (32). To date, there are no comparative studies that show inferior results in terms of potency for LRP compared to RRP. However, it is important to remember that these comparative studies are limited to different patient characteristics and sample sizes.

COST CONSIDERATIONS

In the era of minimally invasive approaches, the economic issues are important. Lotan et al. reported that RRP had a cost advantage of $487 over LRP and $1726 over RALP (33). The cost difference is specifically based on the price of a 1.2 million dollar Da Vinci robotic system (the original system) with a maintenance fee of $100,000 per year (34). There are three robotic systems currently available. The original three-arm system, the four-arm system (approximately 1.4 million dollar) and the new “S-model” (approximately 1.6 million dollar) and high-definition (additional cost) sub-models, each with different purchasing and maintenance costs (maintenance costs are approximately 10% of the purchasing cost). The additional cost of disposables is approximately $2,000 US/case. This is of extreme importance as costs are one of the main factors institutions take into consideration when acquiring new technologies.

The economics of radical prostatectomy in Europe differ from the USA, because of different hospitalization mentality (patients usually stay in the hospital until the urinary catheter is removed in Europe) (24). Using this methodology LRP represented a cost saving of $1237 per case compared to RRP and this is attributed to the reduced hospitalization with LRP (6 days) compared to RRP (8 days) (8).

Although RRP is considered the least expensive at present, LRP related expenses have significantly decreased, which could lead soon, to cost equivalence to RRP. On the other hand, the RALP technique will certainly need a substantial decrease in the cost of the robotic system and other relevant robotic instruments as well as maintenance fees in order to achieve wider global acceptance and application.

The advantages and disadvantages of RRP, LRP and RALP are detailed in Table-3.

CONCLUSIONS

Despite only intermediate term follow-up being available for LRP and RALP techniques, current available data demonstrates that laparoscopic and robotic prostatectomy procedures achieve oncologic and functional outcomes similar to the well established technique of open radical prostatectomy. Indeed, in most studies, better results are achieved with LRP and RALP in terms of blood loss, convalescence and cosmetics when compared to RRP.

However, LRP is associated with a steep learning curve and longer operative time. The RALP technique holds potential for better ergonomics. The initial purchase and maintenance fees for the robotic platform are still expensive. Efforts to reduce the cost for RALP must be materialized for this technique to compete with others worldwide.

After intermediate term follow-up, LRP and RALP techniques have already gained wider acceptance in the treatment of localized prostate cancer. With an expected reduce in the cost and decrease in the learning curve and OR time, minimally invasive prostatectomy techniques have the potential to be the gold standard in the treatment of localized prostate cancer worldwide. However, long term data and adequately designed comparative studies are clearly needed to assess the inherent advantages and disadvantages of the three different techniques.
Comparison of Radical Prostatectomy Techniques

Table 3 – Advantages and disadvantages of RRP, LRP and RALP.

<table>
<thead>
<tr>
<th>RALP</th>
<th>LRP</th>
<th>RRP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td><strong>Advantages</strong></td>
<td><strong>Advantages</strong></td>
</tr>
<tr>
<td>Decreased blood loss</td>
<td>Decreased blood loss</td>
<td>Proven oncological outcomes</td>
</tr>
<tr>
<td>Faster recovery</td>
<td>Faster recovery</td>
<td>Tactile feedback</td>
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<tr>
<td>Better cosmetic results</td>
<td>Better cosmetic results</td>
<td>No additional training required</td>
</tr>
<tr>
<td>Decreased hospital stay</td>
<td>Decreased hospital stay</td>
<td></td>
</tr>
<tr>
<td>Enhanced visibility of vital</td>
<td>Enhanced visibility of vital</td>
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<tr>
<td>structures (i.e. NVB)</td>
<td>structures (i.e. NVB)</td>
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<tr>
<td>Superior ergonomics for the</td>
<td>Superior ergonomics for the</td>
<td></td>
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<tr>
<td>primary surgeon</td>
<td>primary surgeon</td>
<td></td>
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<tr>
<td>Shorter learning curve compared</td>
<td>Shorter learning curve compared</td>
<td></td>
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<tr>
<td>to LRP</td>
<td>to LRP</td>
<td></td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td><strong>Disadvantages</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>No long-term oncological data</td>
<td>No long-term oncological data</td>
<td>Increased blood loss</td>
</tr>
<tr>
<td>High initial and procedural cost</td>
<td>Steep learning curve</td>
<td>Increased length of catheterization (historical series)</td>
</tr>
<tr>
<td>Longer operative time</td>
<td>Longer operative time</td>
<td></td>
</tr>
<tr>
<td>Limited instrumentation</td>
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</tbody>
</table>

CONFLICT OF INTEREST

None declared.

REFERENCES

Comparison of Radical Prostatectomy Techniques


36. Catalona WJ, Carvalhal GF, Mager DE, Smith DS: Potency, continence and complication rates in 1,870
EDITORIAL COMMENT

The authors compare oncologic, functional and cost outcomes between open radical retropubic prostatectomy and the two laparoscopic approaches: pure and robotic-assisted.

They conclude that all outcomes are similar with the exception of costs, which are greater with the use of robotic-assistance. Currently, robotic technology is almost universally available in the United States. This availability has allowed many urologic surgeons to venture into the field of advanced laparoscopic surgery. Robotic technology is also available in many centers in Europe. Nevertheless, several well-established groups continue to perform pure laparoscopic surgery as they have achieved a high level of experience. This experience allows them to perform the surgery with the same oncologic and functional outcomes as with the ones reported with the use of robotic-assistance. Conversely, in Latin America, the majority of laparoscopic prostatectomies are performed by the pure laparoscopic approach due to the lack of access to robotic technology.

This well structured review should be a tempering reminder that, as of present, the reported outcomes for surgery are the same regardless of the approach. The importance of the learning curve and experience in achieving maximal oncologic and functional outcomes should always be remembered. There are currently competing, effective treatments for localized prostate cancer such as the different forms of radiation therapy, cryotherapy, and high intensity focus ultrasound. Therefore, it is incumbent upon the urologic surgeon to remain abreast of improvements in technique, advances in technology and to maintain maximal surgical skills regardless of the approach.

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EDITORIAL COMMENT

For patients diagnosed with prostate cancer, choosing whether and how to treat can be a daunting task. The widespread implementation of minimally invasive surgical approaches has dramatically altered the landscape of treatment options. Short-term perioperative benefits from laparoscopic and robotic-assisted surgery have been definitively established. However, in regard to more meaningful outcomes such as cancer control, urinary continence, and sexual function methodologically sound comparisons to open surgery are lacking (1).

Recognizing the inherent limitations in the published literature (e.g. patient selection, tumor characteristics, and surgeon experience), the authors do an excellent job of concisely and evenhandedly reviewing the three most common surgical approaches to radical prostatectomy. In light of the multiple options, we agree the impact of surgeon skill and experience is likely to be far more important than whether he or she looks at the prostate on a television monitor or via an open incision (2-5).

Further, an honest understanding of the merits and limitations of the individual procedures will only be garnered when validated questionnaires are uniformly used to assess functional recovery and quality of life. The inconsistent use of these metrics coupled with the potential for selection bias skews the available data and accounts for the wide range of reported outcomes.

The percentage of radical prostatectomies performed laparoscopically or robotically has been steadily increasing, from 12% to 31% between 2003 and 2005, and will likely continue to do so (4). However, we must be careful of “gizmo idolatry” and beware of the trap of “the cutting edge or first on the block use of a gizmo” which can “bestow on the physician a mantle of expertise, competence, and pre-eminence even if there is little or no evidence that the patient will benefit” (6). Careful, honest, and diligent review of outcomes, as this and other studies undertake, will be of utmost importance to ensure that we are offering patients the optimal treatment and not just the latest gizmo.

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